104TH CONGRESS
1ST SESSION

S. 1369

To amend the Federal Food, Drug, and Cosmetic Act to facilitate the development, approval, and use of medical devices to maintain and improve the public health and quality of life of individuals, and for other purposes.

IN THE SENATE OF THE UNITED STATES

OCTOBER 31, 1995

Mr. WELLSTONE introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to facilitate the development, approval, and use of medical devices to maintain and improve the public health and quality of life of individuals, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE AND REFERENCE.

(a) SHORT TITLE.—This Act may be cited as the ''Medical Technology, Public Health, and Innovation Act of 1995''.

(b) REFERENCE.—Whenever in this Act an amendment or repeal is expressed in terms of an amendment

to, or a repeal of, a section or other provision, the reference shall be considered to be made to a section or other provision of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321 et seq.).

SEC. 2. FINDINGS; MISSIONS STATEMENT.

(a) FINDINGS.—The Congress finds the following:

(1) While the United States appropriately puts a top priority on ensuring the safety and efficacy of medical technologies that are introduced into the marketplace the administration of such regulatory effort is causing the United States to lose its leadership role in producing innovative, top-quality medical devices.

(2) One of the key components of the medical device regulatory process that contributes to the United States losing its leadership role in medical device development is the inordinate amount of time it takes for medical technologies to be reviewed by the United States Food and Drug Administration.

(3) The most important result of the United States losing its leadership role is that patients in the United States do not have access to new medical technology in a timely manner.

(4) Delayed patient access to new technology results in lost opportunities to save lives, to reduce

hospitalization and recovery time, and to improve the quality of life of patients.

(5) The economic benefits that the United States medical device industry, which is composed principally of smaller companies, has provided through growth in jobs and global trade are threatened by the slow and unpredictable regulatory process at the Food and Drug Administration.

(6) The pace and predictability of the medical device regulatory process, together with a perceived adversarial relationship with the Food and Drug Administration, are in part responsible for the increasing tendency of United States medical device companies to shift research, product development, and manufacturing offshore, at the expense of American jobs, patients, and leading edge clinical research.

(b) MISSION STATEMENT.—This legislation seeks to improve the timeliness, effectiveness, and predictability of the medical device approval process for the benefit of United States patients and the United States economy by—

(1) providing for the use of nationally and internationally recognized performance standards to assist the Food and Drug Administration in determining the safety and effectiveness of medical devices;

(2) facilitating communication between medical device companies and the Food and Drug Administration;

(3) redefining clinical testing requirements to reflect the nature of device evolution; and

(4) targeting the use of Food and Drug Administration resources on those devices that are likely to have serious adverse health consequences.

SEC. 3. PERFORMANCE STANDARDS.

Section 514 (21 U.S.C. 360d) is amended by adding at the end thereof the following new subsection:

''ESTABLISHMENT AND ADOPTION OF OTHER STANDARDS

''(c)(1) The Secretary—

''(A) may establish pursuant to subsection (b) performance standards to assist in determining the safety or effectiveness of class III devices under section 515; and

''(B) may amend or revoke the performance standards established under subparagraph (A).

''(2) The Secretary shall, within 365 days of the date of enactment of this subsection, adopt performance standards established by nationally and internationally recognized standard-setting entities and use the standards when applicable to assist in determining the safety and effectiveness of class III devices under section 515.

''(3) The Secretary may not require, as the condition for approving a premarket approval application under section 515, the conformity of a class III device with a performance standard established or adopted pursuant to paragraph (1) or (2), respectively, if the applicant submits data other than that required by the performance standard to demonstrate a reasonable assurance of the safety and effectiveness of the device.

''(4) The Secretary, in lieu of requiring data demonstrating the conformity of a class III device with a standard described in paragraph (1) and (2), shall accept certification by the applicant that the device conforms with each standard identified in the application.

''(5) The Secretary may revoke the performance standards adopted under paragraph (2).

''(6) A performance standard established under this subsection for a device—

''(A) shall include provisions to provide reasonable assurance of the safe and effective performance of the device;

''(B) shall, where necessary to provide reasonable assurance of the safe and effective performance of the device, include—

''(i) provisions with respect to the construction, components, ingredients, and prop-

erties of the device and the compatibility of the device with power systems and connections to the systems;

"(ii) provisions for the testing (on a sample basis or, if necessary, on an individual basis) of the device or, if it is determined that no other more practicable means are available to the Secretary to assure the conformity of the device to the standard, provisions for the testing (on sample basis or, if necessary, on an individual basis) of the device by the Secretary or by another person at the direction of the Secretary;

"(iii) provisions for the measurement of the performance characteristics of the device;

"(iv) provisions requiring that the results of each or certain of the tests of the device required to be made under clause (ii) demonstrate that the device is in conformity with those portions of the standard for which the test or tests were required; and

"(v) a provision requiring that the sale and distribution of the device be restricted to the extent that the sale and distribution of the device

is restricted under a regulation under section 520(e); and

''(C) shall, where appropriate, require the use and prescribe the form and content of labeling for the proper installation, maintenance, operation, and use of the device.''.

SEC. 4. PREMARKET APPROVAL.

(a) APPLICATION.—Section 515(c) (21 U.S.C. 360e(c)) is amended—

(1) in paragraph (1)—

(A) by striking subparagraph (D); and

(B) by redesignating subparagraphs (E), (F), and (G) as subparagraphs (D), (E), and (F), respectively; and

(2) by adding at the end thereof the following new paragraphs:

''(3)(A) An applicant—

''(i) shall include in an application described in paragraph (1) an identifying reference to any applicable performance standard established or adopted under paragraph (1) or (2) of section 514(c), respectively; and

''(ii) shall include in the application—

''(I) a certification by the applicant as described in section 514(c)(4), that the device

complies with the applicable performance standard; or

''(II) data to support the safety or effectiveness of the device.

''(B)(i) Except as provided in clause (ii), the Secretary may not require an applicant who submits an application for premarket approval for a class III device under paragraph (1) to submit preclinical data and information regarding the device relevant to a performance standard established or adopted under paragraph (1) or (2) of section 514(c), respectively, if such standard defines performance or other specifications for the device, and the applicant certifies that the device conforms to the standard.

''(ii) The Secretary may require an applicant described in clause (i) to submit preclinical data and information regarding a class III device if additional information or data are necessary to protect patient safety.

''(C) The Secretary shall require an applicant who certifies that a device conforms to an applicable performance standard established or adopted under paragraph (1) or (2) of section 514(c), respectively to maintain data demonstrating such conformance for a period of time that is equal to the period of time for the design and expected life of the device and to make the data available to the Secretary upon request.

''(D) The Secretary may deny, withdraw, or temporarily suspend approval of a premarket approval application for a class III device if—

''(i) the Secretary determines that the device does not conform to an applicable performance standard (on which the applicant relied) established or adopted under paragraph (1) or (2) of section 514(c), respectively; and

''(ii) such conformance is considered by the Secretary to be material in approving the device.

''(4) The Secretary shall accept retrospective or historical clinical data as a control or for use in determining whether there is a reasonable assurance of device safety and effectiveness if the data are available and the effects of the device on disease progression are clearly defined and well understood.

''(5) The Secretary may not require the sponsor of an application to conduct clinical trials for a device using randomized controls unless—

''(A)(i) such controls are scientifically and ethically feasible;

''(ii) the effects of the device on disease progression are not clearly defined and well understood as determined by the Secretary; and

''(iii) retrospective or historical data are not available that meet the standards of the Secretary for quality and completeness; or

''(B) such controls are necessary to support specific marketing claims.

''(6) The Secretary may not require in a supplement to a premarket approval application data from randomized clinical trials for a modification to a device if—

''(A) the modification does not substantially and adversely affect safety or effectiveness; and

''(B) the modified device has the same intended use and is intended for similar patient populations as the approved device.''.

(b) ACTION ON APPLICATION.—Section 515(d) (21 U.S.C. 360e(d)) is amended—

(1) in paragraph (1)(A), by striking ''paragraph (2) of this subsection'' each place it appears and inserting ''paragraph (6)'';

(2) by redesignating paragraphs (2) and (3) as paragraphs (6) and (7), respectively; and

(3) by inserting after paragraph (1) the following new paragraphs:

''(2) Each premarket approval application and supplement received by the Secretary under subsection (c) shall be reviewed in the following manner to achieve final

action on the application within 180 days of the receipt of the application:

''(A) The Secretary shall make a determination within 30 days of the receipt of an application filed under subsection (c) of whether the application satisfies the content requirements of paragraphs (1) and (3) of subsection (c) and applicable regulations, and the Secretary shall notify the applicant of the determination and whether the application has been accepted or has not been accepted for review for premarket approval. If the Secretary fails to notify the applicant within the 30-day period that the application is not sufficiently complete to permit a substantive review, the application shall be considered as filed by the Secretary.

''(B) The Secretary shall, within 45 days after the date of the acceptance of an application for review under subparagraph (A)—

''(i) provide the applicant the opportunity for a meeting (or teleconference) with the Secretary to—

''(I) inform the applicant of the general progress and status of the application;

''(II) advise the applicant of deficiencies in the application that have not been communicated to the applicant.

The applicant shall have the right to be informed in writing with respect to the information communicated to the applicant during the meeting or teleconference under subclauses (I) and (II).

''(ii) determine whether an advisory panel should be convened by the Secretary to review the application or to consider an issue related to the application.

''(C) The Secretary shall, within 90 days after the date of the acceptance of an application for review under subparagraph (A) provide an applicant the opportunity for a meeting (or teleconference) with the Secretary to—

''(i) inform the applicant of the general progress and status of the application;

''(ii) review actions taken by the applicant to correct deficiencies identified at the 45-day meeting described in subparagraph (B);

''(iii) advise the applicant of the deficiencies in the application that have not been communicated to the applicant; and

''(iv) review the proposed labeling for the device.

The applicant shall have the right to be informed in writing with respect to the information communicated to the applicant during the meeting or teleconference under clauses (i) through (iv).

''(D)(i) When an advisory panel is convened under subparagraph (B)(ii) to review an application or to consider an issue related to the application, the Secretary shall within 15 days after the close of the advisory panel meeting provide the applicant the opportunity for a meeting (or teleconference) with the Secretary to identify any remaining issues with respect to the approval of the application.

''(ii) If an advisory panel is not convened under subparagraph (B)(ii), the Secretary shall, within 120 days after the date of the acceptance of an application for review under subparagraph (A), provide the applicant the opportunity for a meeting (or teleconference) with the Secretary to—

''(I) inform the applicant of the general progress and status of the application;

''(II) review the actions taken to correct deficiencies identified in the application at the

90-day meeting described in subparagraph (C); and

''(III) advise the applicant of the deficiencies in the application that have not been communicated to the applicant.

''(iii) The applicant shall have the right to be informed in writing with respect to the information communicated to the applicant during the meeting or teleconference under clauses (i) and (ii).

''(E) The Secretary shall, within 150 days after the date of the acceptance of an application for review under subparagraph (A), notify the applicant of the decision of the Secretary to approve or disapprove the application.

''(F) The Secretary shall exclude the time that an applicant takes to respond to the Secretary's requests for additional data or information in determining when the 45-day, 90-day, 120-day and 150-day periods described in subparagraphs (B), (C), (D), and (E) expire.

''(3) To permit better treatment or better diagnoses of life-threatening or irreversibly debilitating diseases or conditions, the Secretary shall expedite the review for devices—

''(A) representing breakthrough technologies;

''(B) offering significant advantages over existing approved alternatives; or

''(C) for which accelerated availability is in the best interest of the public health.

''(4)(A) The Secretary shall annually publish a status report on the premarket clearance or approval of applications and other device submissions.

''(B) The report described in subparagraph (A) shall include—

''(i) a specific statement from the Secretary concerning the performance of the Food and Drug Administration in reducing the backlog in the reviewing of applications for premarket clearance or approval for a device and meeting statutory time limitations applicable to the review of the applications;

''(ii) with respect to devices, data (which shall be provided by the Center for Devices and Radiological Health and each division of the Office of Device Evaluation of the Center for Devices and Radiological Health) on—

''(I) the number of premarket approval applications, supplements, premarket notifications, and applications for investigational device

exemptions, not accepted for filing by the Secretary;

"(II) the total time (beginning on the date of the filing of an application and ending on the date of the clearance or approval of the application) required to review the premarket approval applications, supplements, premarket notifications, and applications for investigational device exemptions;

"(III) the total time (excluding the time periods permitted for an applicant to prepare and submit to the Secretary responses or additional information or data requested by the Secretary) as calculated by the Food and Drug Administration to complete the review of each premarket approval application, supplement, premarket notification, and application for investigational device exemption;

"(IV) the number of adverse decisions made with respect to the applications and supplements described in subclause (II);

"(V) the number of nonapprovable letters for device submissions;

"(VI) the number of deficiency letters for device submissions;

''(VII) the number of times applicants are required to supply information during the review of an application or supplement described in subclause (II); and

''(VIII) the performance of the actions described in paragraph (2), including performance information with respect to the number of premarket approval applications that were or were not reviewed within the time limitations described in such paragraph and the time necessary to carry out each of the actions; and

''(iii) baseline data for the data described in subclauses (I) through (VII) of clause (ii) for the preceding year.

''(5) The Secretary shall complete the review of all premarket approval supplements that do not contain clinical data within 90 days of the receipt of a supplement that has been accepted for filing.''.

(c) ELIMINATION OF PREMARKET APPROVAL OF SUPPLEMENTS.—The Secretary of Health and Human Services shall eliminate premarket approval of supplements that relate to manufacturing and product changes of a device that can be demonstrated through appropriate protocols or other methods to not affect adversely the safety or effectiveness of a device. The Secretary of Health

and Human Services shall require the manufacturer of a device to submit to the Secretary of Health and Human Services any information relied upon to support a device-related change that is not subject to premarket approval of a supplement to an application approved under section 515 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360e). The information shall be made a part of the device master record. The information shall be maintained for a period of time equal to the period of time for the design and expected life of the device, but not less than 2 years after the date of release of the device for commercial distribution by the manufacturer.

SEC. 5. PREMARKET NOTIFICATION REQUIREMENTS.

(a) EXEMPTION FOR CLASS I AND II DEVICES.—Section 510 (21 U.S.C. 360) is amended by adding at the end thereof the following new subsection:

''(l) Within 365 days of the date of enactment of this section, the Secretary shall exempt from the notification requirement under subsection (k) class I and II devices that should not be subject to the notification requirement because such notification is not necessary to provide a reasonable assurance of the safety and effectiveness of the devices. Prior to making such determination, the Secretary shall provide an opportunity for notice and comment with

respect to the appropriateness of the exemption for the class I and II devices.''.

(b) LIMITATION ON NOTIFICATION.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall not enforce the requirement for additional notifications under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) for a change or modification to a device initially classified under section 513(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360c(f)) that—

(A) is other than a major change or a major modification in the intended use;

(B) is supported by nonclinical data or information, when appropriate; and

(C) can be shown to not adversely affect the safety and effectiveness of the device.

(2) MAINTENANCE OF NOTIFICATION DATA.—The Secretary of Health and Human Services shall require the manufacturer of a device to submit to the Secretary of Health and Human Services all data and information relied upon to document that a change or modification of a device described in paragraph (1) does not require an additional notification under section 510(k). The data and informa-

tion shall be made a part of the device master record. The data and information shall be maintained for a period of time equal to the period of time for the design and expected life of the device, but not less than 2 years after the date of release of the device for commercial distribution by the manufacturer.

SEC. 6. INVESTIGATIONAL DEVICE EXEMPTION.

(a) REGULATIONS.—Section 520(g) (21 U.S.C. 360j(g)) is amended—

(1) by redesignating paragraphs (4) and (5) as paragraphs (5) and (6), respectively; and

(2) by inserting after paragraph (3) the following new paragraph:

''(4) The Secretary shall, within 120 days of the date of enactment of this paragraph, by regulation amending the content of part 812 of title 21 of the Code of Federal Regulations, amend the procedures with respect to the approval of studies under this subsection as follows:

''(A) The regulation shall include provisions that require the Secretary to permit the sponsor to meet with the Secretary prior to the submission of an application to develop a protocol for a study subject to the regulation, that require that the protocol shall be agreed upon in writing by the sponsor and

the Secretary, and that set forth a time limitation for the sponsor to conduct a followup of a study.

''(B) The regulation shall require the Secretary to permit developmental changes in devices subject to the regulation in response to information gathered during the course of an investigation without requiring an additional approval of an application for an investigational device exemption, or the approval of a supplement to the application, if the changes meet the following requirements:

''(i) The changes do not constitute a significant change in the design of the product or a significant change in basic principles of operation.

''(ii) The changes do not adversely affect patient safety.

The regulation shall require that such a change be documented in records the applicant is required to maintain with respect to the investigational device exemption.

''(C) The regulation shall provide for the use of an investigational device for diagnosis or treatment use under a protocol or investigational device exemption if the following requirements are met:

''(i) The device is intended to treat or diagnose a serious or immediately life-threatening disease.

''(ii) There is no comparable or satisfactory device or other therapy available to treat or diagnose that disease in the intended patient population.

''(iii) The device is under investigation in a controlled clinical trial under an investigational device exemption in effect for the trial or all clinical trials for the device have been completed.

''(iv) The sponsor of the controlled clinical trial is actively pursuing marketing approval of the investigational device with due diligence.

''(D) The regulation shall require the Secretary to consult with advisory panels, which have the appropriate expertise, with respect to the establishment of an appropriate time limitation for the conduct of a followup study by the sponsor of the study.

(b) CONFORMING AMENDMENTS.—Section 517(a)(7) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360g(a)(7)) is amended—

(1) by striking ''section 520(g)(4)'' and inserting ''section 520(g)(5)''; and

(2) by striking ''section 520(g)(5)'' and inserting ''section 520(g)(6)''.

SEC. 7. ESTABLISHMENT OF A POLICY AND PERFORMANCE REVIEW PANEL.

Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 901 et seq.) is amended by adding at the end thereof the following new section:

''SEC. 906. POLICY AND PERFORMANCE REVIEW PANEL.

''(a) ESTABLISHMENT.—There is established a panel to be known as the Food and Drug Policy and Performance Review Panel (hereafter referred to in this section as the 'Panel').

''(b) MEMBERSHIP.—The members of the Panel shall be appointed by the Secretary in accordance with subsection (d)(1) and shall include—

''(1) individuals with expertise in medical, scientific, and health policy and regulatory issues;

''(2) representatives of industry, voluntary health associations, and patient advocacy groups; and

''(3) representatives of the Food and Drug Administration.

''(c) TERMS.—

''(1) IN GENERAL.—Each member of the Panel shall serve for a term of not more than 3 years and

the terms of office of such members shall be staggered.

''(2) REAPPOINTMENT.—Each member of the Panel may be reappointed, but may not serve more than 3 consecutive terms.

''(3) VACANCIES.—Any vacancy in the Panel shall not affect the powers of the Panel and shall be filled in the same manner as the original appointment.

''(d) ORGANIZATIONAL STRUCTURE.—

''(1) IN GENERAL.—The Chairperson of the Panel shall organize the Panel in a manner that will ensure that there is a portion of the membership of the Panel monitoring the activities of each Center within the Food and Drug Administration. The membership of the Panel shall be composed of individuals with expertise necessary to ensure appropriate review of the performance of each Center.

''(2) DEFINITION.—For the purposes of this section, the term 'Center' means the Center for Devices and Radiological Health, Center for Drug Evaluation and Research, Center for Biologics Evaluation and Research, Center for Food Safety and Applied Nutrition, Center for Veterinary Medicine, and Center for Toxicological Research.

''(e) CHAIRPERSON AND VICE CHAIRPERSON.—The Secretary shall select a Chairperson and Vice Chairperson from among the members of the Panel.

''(f) INITIAL MEETING.—Not later than 30 days after the date on which all members of the Panel have been appointed, the Panel shall hold its first meeting.

''(g) MEETINGS.—The Panel shall meet at the call of the Chairperson.

''(h) QUORUM.—A majority of the members of the Panel shall constitute a quorum, but a lesser number of members may hold hearings.

''(i) DUTIES.—The Panel shall—

''(1) monitor the activities carried out by the Secretary through the Commissioner of Food and Drugs;

''(2) review the performance of the Food and Drug Administration to determine if the Food and Drug Administration is carrying out its mission to protect and promote the public health and is developing appropriate policy and effective regulations to carry out its mission;

''(3) review the performance of each Center in accordance with subsection (d)(1);

''(4) meet at least twice annually with appropriate management officials of the Food and Drug Administration and representatives of each Center;

''(5) participate in the development of agency guidelines; and

''(6) seek to facilitate the international harmonization of regulatory requirements, while ensuring that a product that is subject to the provisions of this Act, and that is marketed in the United States, is safe and effective.

''(j) REPORT.—The Panel shall annually prepare and submit to the Committee on Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report that evaluates the performance of the Food and Drug Administration (including a description of the activities that the Food and Drug Administration has successfully or unsuccessfully carried out) and includes a recommendation on the administrative modifications needed to improve such performance.

''(k) HEARINGS.—The Panel may hold such hearings, sit and act at such times and places, take such testimony, and receive such evidence as the Panel considers advisable to carry out the purposes of this Act.

''(l) INFORMATION FROM FEDERAL AGENCIES.—The Panel may secure directly from any Federal department

or agency such information as the Panel considers necessary to carry out the provisions of this Act. Upon request of the Chairperson of the Panel, the head of such department or agency shall furnish such information to the Panel.

''(m) POSTAL SERVICES.—The Panel may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

''(n) DETAIL OF GOVERNMENT EMPLOYEES.—Any Federal Government employee may be detailed to the Panel without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

''(o) PROCUREMENT OF TEMPORARY AND INTERMITTENT SERVICES.—The Chairperson of the Panel may procure temporary and intermittent services under section 3109(b) of title 5, United States Code, at rates for individuals which do not exceed the daily equivalent of the annual rate of basic pay prescribed for level V of the Executive Schedule under section 5316 of such title.

''(p) TERMINATION OF THE PANEL.—The termination provisions of section 14 of the Federal Advisory

Committee Act (5 U.S.C. App.) shall not apply to the Panel.''.

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